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(54) Kunststoffüberzoge .tallgitterstents

Die vorliegende Erfindung betrifft Metallgitterstents zur permanenten Dehnung von arteriellen Verengungen, die mit einem dünnen Überzug aus Polytetrafluorethylen überkleidet sind.

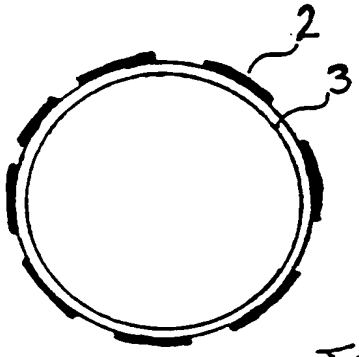

Fig. 2

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Beschreibung

Gegenstand der Erfindung sind kunststoffüberzogene Metallgitterstents zur permanenten Dehnung von arteriellen Verengungen.

Nach transluminaler Dehnung von arteriellen Stenosen mit einem Ballonkatheter oder nach Wiedereröffnung komplett verschlossener Gefäße kann in vielen Fällen das Lumen nicht bleibend offen gehalten werden, da sich Teile der Intima wie ein Ventil verschließend nach innen legen.

Dies führt bei bestimmten Lokalisationen (z.B. der Koronararterien) zu einer kritischen Situation, die eine notfallmäßige Bypass-Operation mit hohem Risiko für den Patienten erforderlich macht; in jedem Fall verhindert es jedoch den angestrebten Akuterfolg.

Seit einigen Jahren wird mit Gefäßendoprothesen, sogenannten Stents, experimentiert, die aus einem Geflecht von Metalldrähten (meist in Gitterform) bestehen und entweder als selbstexpandierende (aktive) Stents (Sigwart, U., Puel, J. Mirkovitch, V., Joffre, F., Kappenberger, L.: "Intravascular stents to prevent occlusion and restenosis after transluminal angioplasty", New Engl. J. Med. 316, 701 (1987) und Palmaz, J.C., Richter, G.M., Noeldge, G. et al: Intraluminal stents in atherosclerotic iliuc artery stenoses. Preliminary report of an multicenter study, Radiology 168 (1988), 727) oder mit dem Ballonkatheter an Ort und Stelle aufzudehnende (passive) Stents (Strecker, E.P., Romaniuk, R., Schneider, B., Westphal, M., Zeitler, E., Wolf, H.R.D., Freudenberg, N.: Perkutan implantierbare, durch Ballon aufdehnbare Gefäßprothese DMW 113 (1988), 538) vorliegen und als innere Stütze das Gefäß offenhalten.

Obwohl diese Gefäßendoprothesen aus einem blut- und gewebeverträglichen Material, z.B. vergoldetem Stahldraht, hergestellt werden, weisen sie jedoch eine nicht zu unterschätzende Thrombogenität auf, der, um Frühverschlüsse zu vermeiden, mit hohen (potentiell gefährlichen) Dosen von gerinnungshemmenden Medikamenten begegnet werden muß. Danach, d.h. in wenigen Wochen, werden die Metalldrähte durch die Gefäß-Innenhaut, das Endothel, überwachsen, so daß eine glatte, relativ athrombogene Oberfläche entsteht. Die Hoffnung , die Rate der Rezidive durch die Einlage solcher Gefäßendoprothesen senken zu können, hat sich jedoch bisher nicht bestätigen lassen (Mahler, F., Do, D., Triller, J., Thalmann, R., Walpoth, B.:Verlaufsergebnisse nach perkutaner Einlage arterieller Endoprothesen (stents) in die Beinarterien, VASA, Suppl. 23, 176 – 177 (1988). Das Problem scheint in der Durchwachsung des Gitters durch Gewebszellen zu sein. Deren Wachstum, welches durch das eingeführte Stent stimuliert wurde, hört nämlich nicht nach vollständiger Umkleidung des Geflechts auf, sondern geht weiter und kann dadurch zu einem erneuten vollständigen oder teilweisen Verschluß des Gefäßes führen.

Aufgabe der vorliegenden Erfindung war es daher, eine Gefäßendoprothese zu entwickeln, welche einerseits ein verengtes Gefäß dauerhaft aufweitet; andererseits nicht thrombogen wirkt und eine Durchwachsung durch Gewebszellen verhindert.

Diese Aufgabe wird überraschenderweise gelöst, indem man ein an sich bekanntes Metallgitterstent innen (und eventuell außen) mit einem dünnen Überzug aus Polytetrafluorethylen (PTFE oder PTF) überkleidet.

Polytetrafluorethylen, ein Polymerisat der Formel $-(CF_2-CF_2)_n-$ mit $n = 5000-100\,000$ ist ein bekanntes Produkt, welches aufgrund seiner großen chemischen Beständigkeit in großem Umfang für vielfältige Beschichtungen und Auskleidungen im chemischen Apparatebau verwendet wird. Seit einiger Zeit findet dieses Material auch medizinische Anwendung zur Beschichtung von Gelenkprothesen. Seit längerem werden dünne Schläuche aus PTFE mit großem Erfolg auch als Gefäßprothesen (Bypässe) eingesetzt. Eine spezielle mikroporöse Struktur sorgt für ein organisches Verwachsen der Enden mit den zu verbindenden Gefäßen.

Erfindungsgemäß wird entweder eine Dispersion aus PTF um ein entsprechendes Stent aus Metallgitter herumgesintert oder eine sehr dünne, von einem Block aus PTF abgeschälte Folie von innen in das Stent eingelegt und unter Erwärmen bis zu 370 – 380°C und/oder unter Anwendung von Druck mit dem Stent verbunden. Gegebenenfalls kann eine weitere Folie von außen um das Stent gelegt werden, um eine vollständige Einschließung des Metalls zu erreichen. Die Folie kann gegebenenfalls auch zu einem Schlauch vernäht werden.

Auf diese Weise wird die Thrombogenität, die zu Frühverschlüssen führen kann und die Durchwachsbarkeit, die die Spätverschlüsse der Gefäßendoprothesen bewirkt, vermieden.

Da das Metall des Stents somit nicht mehr mit dem Blut und dem Gewebe in Berührung kommt, kann das Geflecht aus relativ preiswertem Stahldraht, vorzugsweise einem rostfreien Stahl, bestehen, wobei natürlich auch gewebeverträgliche Metalle genügender Härte wie Titan oder Edelmetalle eingesetzt werden können.

Die erfindungsgemäßen Stents werden in üblicher Weise über einen in das Gefäß eingebrachten Katheter in die verengte Stelle eingebracht. Damit der Stent dabei das Gefäß passieren kann, muß er vorher nach Möglichkeit um den Katheter komprimiert werden, um erst am Wirkort durch die eigene Spannkraft oder mit Hilfe eines Ballon-Katheters auf die benötigte Weite ausgedehnt zu werden.

Die vorgeformte endgültige Weite beginnt bei etwa 2 mm Durchmesser, größere Durchmesser von z.B. 3 – 12 mm ermöglichen den Einsatz in anderen Gefäßgebieten (z.B. Bein-, Becken- oder Nierenarterien, Aorta, Halsschlagadern, Koronararterien usw.).

Während die bekannten, nur aus einem Metallgitter bestehenden Stents dehnbar sind und sich zusammendrücken oder durch Längsdehnung im Querschnitt verengen lassen, ist der erfindungsgemäße PTFE-Überzug nicht bzw. nur sehr wenig dehnbar. Die notwendige Querschnittsverringerung beim Einführen in das Gefäß wird daher vorzugsweise durch eine oder mehrere Längsfalten erreicht und der ursprüngliche Querschnitt durch Dehnung mit einem Ballon-Katheter erreicht, wobei die Falte ausgeklappt wird. Alternativ kann bei einer schraubenförmigen Metalleinlage die Querschnittsverengung durch Verdrillen erzeugt werden. Die Erfindung soll jedoch nicht auf diese Ausführungsformen beschränkt sein.

Die notwendige Flexibilität des Stents wird durch den PTFE-Überzug nicht beeinträchtigt; dies ist für den Einschub in Gefäßbiegungen wichtig.

In den folgenden Figuren ist die Erfindung näher erläutert, ohne daß diese dadurch begrenzt sein soll.

Fig. 1 zeigt ein konventionelles Metallgitterstent.

Fig. 2 zeigt ein Metallgitterstent mit PFTE-Innenauskleidung.

Fig. 3 zeigt ein Metallgitterstent mit Innenauskleidung in komprimiertem Zustand.

Fig. 4 zeigt ein Metallgitterstent mit Innen- und Außenbelag von PTFE.

Im einzelnen zeigt die **Fig.** 1 ein konventionelles Metallgitterstent, wobei aus dünnen Drähten, die beispielsweise aus Tantal oder einem Edelmetall bestehen können, ein Schlauch (1) gewirkt ist, dessen Drahtmaschen (2) zur Einführung in ein Gefäß komprimiert oder in die Länge gezogen werden können, so daß sich der Querschnitt des Stents verringert. Nach Einbringen in das Gefäß kann das Stent dann auf den Gefäßdurchmesser wieder aufgeweitet werden.

Die **Fig.** 2 zeigt ein entsprechendes Metallgitterstent (1) im Querschnitt, wobei die Metalldrahtmaschen (2) durch dicke und dünne Umfangslinien angedeutet sind. Das Stent ist innen mit einer PTFE-Schicht (3) ausgekleidet, wobei aus zeichentechnischen Gründen ein Abstand zu den Drahtmaschen (2) angedeutet ist, im Gebrauch liegen Schlauch und Maschen allerdings eng aneinander.

In **Fig.** 3 ist ein entsprechender Stent (1) aus Tantaldraht (2) mit einer Innenauskleidung aus PTFE (3) in komprimiertem Zustand abgebildet, was dadurch angedeutet ist, daß die Metalldrahtmaschen sich fast berühren. Der PTFE-Innenschlauch ist zum Ausgleich des verringerten Umfangs mit einer zusätzlichen Falte (4) abgebildet, welche sich beim Ausdehnen des Stents, wie in **Fig.** 2 dargestellt, glatt an das Metallgitter anliegt.

In **Fig.** 4 ist ein weiterer Metallgitterstent (1) mit einem Innenschlauch (3) und einem Außenmantel (5) wiedergegeben. Je nach Herstellungsweise sind diese beiden PTFE-Hüllen zwischen den Drahtmaschen (2) miteinander verbunden.

Patentansprüche

1. Metallgitterstents zur permanenten Dehnung von arteriellen Verengungen, **dadurch gekennzeichnet,** daß sie an der Innenseite mit einem dünnen Überzug aus Polytetrafluorethylen überkleidet sind.
2. Metallgitterstents gemäß Ansruch 1, dadurch gekennzeichnet, daß Innen- und Außenseite mit PTFE überkleidet sind.
3. Metallgitterstents gemäß Anspruch 1, dad[illegible] gekennzeichnet, daß der Überzug als Folie a[illegible] Metallgitter aufgesintert oder als Schlauch am[illegible] um dasselbe vernäht ist.
4. Metallgitterstents gemäß Anspruch 2, dadurch gekennzeichnet, daß zwei Folien um das Metallgitter herum aneinander gesintert sind.
5. Metallgitterstents gemäß Anspruch 2, dadurch gekennzeichnet, daß eine PTFE-Dispersion auf das Metallgitter aufgebracht und zu einem Überzug zusammengesintert ist.
6. Metallgitterstents gemäß Ansprüchen 1 – 5, dadurch gekennzeichnet, daß der Querschnitt des Stents über eine Längsfalte veränderbar ist.
7. Metallgitterstents gemäß Ansprüchen 1 – 5, dadurch gekennzeichnet, daß der Querschnitt über eine longitudinale Verdrillung veränderbar ist.

Hierzu 1 Seite(n) Zeichnungen

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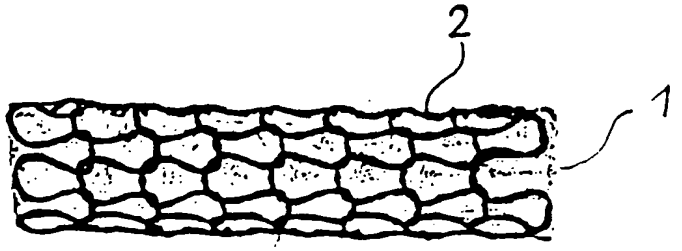

Fig. 1

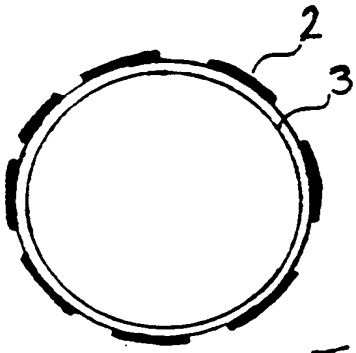

Fig. 2

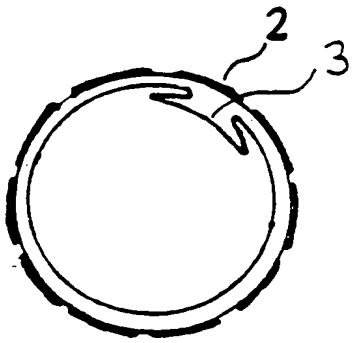

Fig. 3

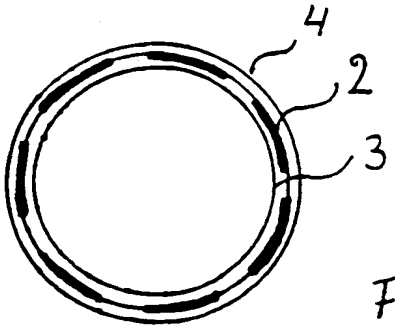

Fig. 4

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WPI Acc No: 90-377029/199051
XRAM Acc No: C90-164238
XRPX Acc No: N90-287321
PTFE coating for metal mesh prosthesis used in artery expansion - internal and external coatings are applied to mesh and prevent thrombosis and further arterial restriction
Patent Assignee: VALLBRACHT C (VALL-I)
Inventor: VALLBRACHT C
Number of Countries: 001 Number of Patents: 002
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Main IPC	Week
DE 3918736	A	19901213	DE 3918736	A	19890608		199051 B
DE 3918736	C2	19980514	DE 3918736	A	19890608	A61L-027/00	199823

Priority Applications (No Type Date): DE 3918736 A 19890608
Patent Details:

Patent	Kind	Lan	Pg	Filing Notes	Application	Patent
DE 3918736	A		4			
DE 3918736	C2		4			

Abstract (Basic): DE 3918736 A
A prosthesis is described which consists of an expandable metal wire mesh (2). The prosthesis has a thin coating (3) of polytetrafluoroethylene on the inner surface. A further coating (4) can if necessary be applied to the outer surface. The PTFE (3) can be applied to the mesh (2) as a film and sintered, as a tube which can be stitched around the mesh (2) or as a dispersion which is sintered.
USE/ADVANTAGE - As a prosthesis for insertion into restricted arteries for maintaining a constant expansion of the restricted canal. Onset of thrombosis is prevented and cell growth through the grid is prevented thus avoiding further arterial restriction. (4pp Dwg.No.2/4)
Title Terms: PTFE; COATING; METAL; MESH; PROSTHESIS; ARTERY; EXPAND; INTERNAL; EXTERNAL; COATING; APPLY; MESH; PREVENT; THROMBOSIS; ARTERY; RESTRICT
Derwent Class: A96; D21; P32; P34
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(54) SURGICAL DILATORS AND SPECIFICALLY AN ESOPHAGEAL DILATOR

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Agent: Kessler Agency

(30) Conventional Priority:

(32) (33) (31) *Patent, the granting of which was deferred in compliance with Article 11, § 7, of the law of July 5, 1844, amended by the law of April 7, 1902.*

The present invention pertains to surgical dilators and specifically to an esophageal dilator.

According to the present invention, a surgical dilator is produced, which comprises a hollow tubular element, whose wall is defined by a tubular framework in the form of a lattice, which [framework] is coated with a continuous layer of elastic material, the dilator being such that, when it is subjected to an axial tensile force, the wall contracts diametrically and extends axially, with this wall more or less resuming its normal shape when the force is no longer applied.

According to the present invention, a surgical dilator, which comprises a hollow tubular element, whose wall is defined by a tubular framework in the form of a lattice, is also produced, with the elements forming the lattice delimiting diamond shapes, with each diamond shape having its large diagonal directed along the longitudinal axis of the wall when the dilator is in the relaxed state, and this dilator is such that, when it is subjected to an axial tensile force, the wall contracts diametrically and extends axially, with this wall more or less resuming its normal shape when the force is no longer applied.

Preferably, the acute angle of each diamond shaped by the elements in the relaxed state of the dilator is between 45° and 60°.

The features and advantages of the present invention will become apparent from reading the description which follows, with the embodiments of same only representing simple examples in relation to the attached drawings, in which:

- Figures 1 to 5 schematically show different embodiments of the dilator, and the elastic layer, in which the framework is embedded, has been removed for the purpose of clarity; Figures 2 and 4 are partial views of the framework;
- Figure 6 is a cross section of Figure 1, showing the framework and the elastic layer;
- Figure 7 schematically shows a pair of extending forceps for inserting the dilator into an esophagus in conjunction with an esophagoscope;
- Figure 8 schematically shows an instrument for inserting the dilator in an esophagus; and
- Figure 9 schematically shows, in a sectional view, a sheath covering the dilator.

Referring to Figure 1, the dilator comprises a hollow tubular element, the wall of which is defined by a tubular framework 1 in the form of a lattice that is coated with a continuous tubular layer 3 (see Figure 6) of elastic material, such as rubber. The elements 2, which form the lattice, may be produced with a stainless-steel wire, a nylon monofilament, a glass fiber monofilament, or with other synthetic materials, and are woven or braided in a helical manner, such that, when the dilator is in the relaxed state, they delimit diamond shapes, the large diagonal of which is in the direction of the longitudinal axis of the wall of the dilator; the acute angle of each of the diamonds shaped by the elements in the relaxed state of the dilator is between 45° and 60° because the low value desired for the ratio between the axial extension and the variation in diameter of the dilator is obtained in this range. Low values must be obtained for this ratio when the dilator must be used in an esophagus due to the fact that only low axial extensions of this dilator can be tolerated. However, in cases, in which high axial extensions are possible, acute angles capable of reaching 90° may be used.

In order to permit the insertion of the dilator into an esophagus, e.g., loops 4 (see Figure 7) are formed at each end of the framework 1, as will become apparent later in the description, to make possible the application of an axial tensile force to the dilator using an extending instrument in order to contract the latter diametrically and to extend it axially; these loops are covered with rubber and may be formed by the ends of the framework 1, or they may be separate elements fixed to this framework. Precautions must be taken, so that the loops do not tend to curve towards the interior of the framework, in which case they would block the passage of the dilator.

The tensile strength and the diameter of the wire, the number of the wires used and the size of the weaving, as well as the elasticity of the layer, define the physical characteristics of the dilator. By selecting these factors, it is possible to produce a variety of useful dilators, having different lengths and diameters.

The ends of the steel wire of the framework may be connected by swaging or by welding in order to obtain a rigid or elastic end or, if the ends are formed without connection, i.e., if the framework 1 is formed by only one wire, the orifices 1a of the dilator may take the shape of a bell.

In a variant (see Figure 2), the framework 1 is formed by wires 2, which

are neither woven nor braided, but are assembled by crimping to form the lattice structure, which is then coated with a layer of elastic material.

Referring to Figure 3, the framework 1 is formed by articulated blades 2, e.g., made of stainless steel, nylon, etc., which are subjected to the tension exerted by the springs 2a, which tend to dilate the dilator diametrically, and which are, yet again, coated with a continuous layer of elastic material.

Figure 4 again shows another shape of the framework 1, which is formed by a simple molding of nylon or other plastic material or of rubber. This type of framework may tend to sag and form a sort of slit sheath, in which case a wire reinforcement may be used and/or the elements forming the winding may be given an elliptical cross configuration so that the framework resists such a tendency to sag.

According to another variant (see Figure 5), the framework 1 is formed by two helical springs, which are placed one inside the other and are wound in the opposite direction, in order to form a lattice structure, and this structure is, yet again, coated with a layer of elastic material.

In order to introduce the dilators described above into the esophagus of a patient, e.g., a pair of traction forceps is used (see Figure 7) in conjunction with a standard esophagoscope [sic, Tr.Ed.] (not shown). The forceps 5 comprise projecting parts 6 similar to hooks, intended for hooking onto the corresponding loops located at the ends of the dilator, and rods 7 sliding in relation to one another, in order to apply an axial force to the dilator, when it is hooked onto the projecting parts 6, in order to extend it axially. In its elongated state, the dilator is able to pass through the esophagoscope arranged in the esophagus, and when the forceps are removed from the dilator, it [dilator] tends to resume its relaxed shape and consequently to press towards the outside against the wall of the esophagus. The forceps and the esophagoscope are then able to be removed from the esophagus.

According to another process for inserting the dilator, an instrument 10 is used (see Figure 8). This instrument differs from the standard esophagoscope shape in the sense that a dilator, as described above, is fixed to the furthest end of the esophagoscope 12, and may be extended or contracted axially by means of a manually maneuverable control 11. To insert a dilator, the instrument is introduced in the esophagus with an internal seal 13. The seal is then removed, and a separate dilator is lubricated and introduced into the wide end closest to the instrument and then pushed towards the furthest end, which, since it is much narrower, forces this dilator to take its elongated shape. The dilator is then extruded to the desired level, while the instrument is removed. To remove the dilator, the instrument is introduced again, and its end dilator is widened and gradually slides around the end of the dilator arranged in the esophagus, so as to make it possible for it to be pulled into the end of the instrument, after which it may be taken hold of using a pair of forceps 5, pulled in an extended state, and removed simultaneously with the instrument 10.

According to yet another insertion process, the dilator is enclosed, prior to its insertion, in a contracting cylindrical cover 15 (see Figure 9), which is made, e.g., of a plastic material, so that it [the dilator] is maintained in its state of axial extension. A seal is then introduced into the dilator, in order to fit into its furthest end and the seal and the dilator are then inserted into the esophagus, after which the cylinder is withdrawn, which enables the dilator to dilate diametrically and the seal to be removed. The usages of the dilators described above in the esophagus are as follows:

1. DILATION

(I) For malignant stenoses:

They [dilators] are used here as a final measure in inoperable cancers to make it possible for the patient to swallow better, due to the fact that they have a passage that is wider than the Forges, Mouseau Babin or Célestin tubes, and they are continuously dilated. The tendency towards blockage is lower, and the patient is able to swallow liquid or soft food more naturally and with less dependence. Because of the tendency to exert a pressure towards the outside, as well as the bell-shaped ends, there is less tendency to slide downwards into the esophagus. The dilator used under these conditions may have more elastic layer free from the framework at the ends in order to make possible a better adherence to the wall of the esophagus.

These dilators may also be suitable as means for fixing radioactive wires in order to deliver a measured dose to a certain part of the esophagus.

(II) For benign stenoses, including:

1. Post-traumatic stenoses following:

(a) surgical operations or anastomoses of the esophagus;
(b) the swallowing of a highly caustic material with resulting scar;
(c) irradiation or radiation therapy for cancer of the lung or esophagus, etc.

2. Congenital stenoses. Small dilators, which are less likely to cause damage and subsequent scars than the conventional dilation procedures, may be used in the rare cases of true congenital stenoses.

3. Stenoses resulting from esophageal reflux associated with insufficient cardioesophageal junction or hiatal hernia. To prevent the reflux of acid after an operation or treatment of the hernia, or after vagotomy and drainage of the stomach, a slight dilation of the stenosis is made practical using this process.

2. ESOPHAGEAL VARICES

To control the bleeding of esophageal varices, as an emergency procedure, instead of the conventional Sengstaken tube, when it is indicated.

The dilator, with a constant pressure towards the outside (using a dilator having the proper dimensions and elasticity), is able to produce the same effect as the Sengstaken tube, without having the drawbacks, which are:

a. a tube extending along the entire length of the mouth, the pharynx and the esophagus;

b. the risk of pneumonia due to inhalation, as a result of the incapacity to swallow saliva;

c. the obstruction to vomiting;

d. difficulties in feeding through the narrow passage of the Sengstaken tube; and

e. the fact that the pressure of the tube must be monitored constantly, and that this tube must be deflated every six hours.

By using the dilator of the present invention, the esophageal varices are able to be compressed in order to ensure hemostasis, while a wide passage makes it possible for the patient to swallow or to vomit, depending on circumstances, or the passage of tubes for the lavage of the stomach.

Provided that it is properly extended and has appropriate dimensions, the dilator may be left in place without any risk for long periods of time, which may be a week in the acute phase, to control the bleeding, while the patient is prepared for a more definitive subsequent operation. In this case, alkalis are used to prevent the esophageal reflux.

Employing the same principle as for the esophagus, the dilators described above may also be used as:

dilators of the urethra;
common bile duct and dilators of the common hepatic duct;
dilators of wounds;
vaginal dilators.

Any orifice or hollow organ that is scarred and physiologically stenosed may be dilated using this process, which makes possible:

a. a reduction to a minimum of damage caused to the epithelial surface;

b. a slow continuous stretching over a long period of time, avoiding the traumatic effects of an abrupt stretching with the minimum formation of scar tissue. Premature recurrent stenosis is thus reduced to a minimum.

In addition, the dilators may be used to support grafts, or hollow organs and blood vessels, etc. during the suture; equipped with points 16 (see Figure 6), they are able to support the organ by the inside and thus avoid the suture in some cases.

The instrument 10, which is equipped with a remote control, may also be employed instead of the conventional bougies for a transient dilation.

In addition, with controls arranged at four points on the circumference or even at three points, the furthest end of the dilator may be moved in an oblique direction to explore the contours in any direction; fiber optics may be combined in such an instrument.

Of course, the present invention is not limited to the terms of the above description, but it does, on the contrary, comprise all its variants within the capability of a person skilled in the art.

A B S T R A C T

The object of the present invention is:

A) A surgical dilator comprising a tubular element, whose wall is defined by a tubular framework in the form of a lattice, coated with a continuous layer of elastic material, with this dilator being such that, when it is subjected to an axial tensile force, its wall contracts diametrically and it extends axially, and this wall more or less resumes its normal shape, when the force is no longer

applied, with the said dilator being additionally characterized by the following points taken alone or in combination:

1) The elements forming the lattice delimit diamonds, with each [diamond] having its large diagonal directed along the longitudinal axis of the wall when the dilator is in the relaxed state;

2) The said framework is coated with a said continuous layer of elastic material;

3) The acute angle of each diamond formed by the elements in the relaxed state is between 45° and 60°;

4) The framework is made of a woven or braided filament material;

5) The framework is formed by wires assembled by crimping;

6) The framework is formed by two helical springs, which are arranged one inside the other and are wound in opposite directions;

7) The framework is formed by articulated blades that are subjected to the tension exerted by the springs, which tend to dilate the dilator diametrically;

8) The framework is metallic;

9) The framework is formed by a molding of a plastic material;

10) One of the ends of the tubular element is bell-shaped;

11) Loops are provided at the ends of the tubular element in order to make it possible to apply an axial tensile force to the said element;

12) The outer surface of the tubular element is provided with points;

13) It [the dilator] comprises a removable cover, which surrounds the said tubular element and supports it in the state of axial extension;

B) A surgical instrument comprising an esophagoscope, a surgical dilator according to A), fixed to the furthest end of this esophagoscope, and manual control means for the axial extension of the said dilator.

Sheet 1/II
Figure 1
through
Figure 9